DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Olympus America, Inc.
Laura Storms-Tyler
Director, Regulatory Affairs
Two Corporate Center Drive
Melville, NY 11747-3157

JUL 27 2015

Re: K012074
Trade/Device Name: XBO1-824-18/19/20 Biopsy Forceps
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCZ, FCF, FCT
Dated (Date on orig SE ltr): June 29, 2001
Received (Date on orig SE ltr): July 2, 2001

Dear Ms. Storms-Tyler,

This letter corrects our substantially equivalent letter of September 25, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K012074

510(k) Number (if known):

Device Name: BIOPSY FORCEPS

Indications for Use:

Olympus BIOPSY FORCEPS has been designed to be used with an Olympus endoscope to collect tissue samples within the upper and lower digestive tract and to extract the tissue samples though the biopsy forceps with suction.

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012074

Concurrence of CDRH, Office of Device Evaluation ODE

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 876.4400)

(Optional Format 1-2-96)

K012074

SEP 2 5 2001

510(k) SUMMARY

XBO1-1-824-18/19/20
Biopsy Forceps

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Section807.92.

A. Submitter's Name, Address, Phone and Fax Number

1. Manufacturer of the subject device

Name & Address of Manufacturer;	Olympus Optical Co,. Ltd. 2-3-1 Shinjuku Monolis Nishi-shinjuku Shinjuku-ku, Tokyo, 163-0914 Japan
Registration No :	8010047
Address, Phone and Fax Number of R&D Department Endoscope Division	2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan TEL 81-426-42-5177 FAX 81-426-46-5613

2. Name of Contact Person

Name :	Ms.Laura Storms-Tyler Director, Regulatory Affairs Olympus America Inc. Two Corporate Center Drive Melville, NY 11747-3157
Address, Phone and Fax :	TEL (631)844-5688 FAX (631) 844-5416

B. Device Name, Common Name

1. Device Name :	XBO1-824-18/19/20 Biopsy Forceps
2. Common/Usual Name :	Biopsy Forceps
3. Classification Name :	21CFR 876.1075 21CFR 876.1500

K012074

C. Predicate Devices:

Model	Device Description & 510(k)#/ Date Cleared	Manufacturer
Multiple Biopsy Device MBx	#K911448 04/16/1991	Triton Technology
FB Series Biopsy Forceps	#K955065 01/24/1996	Olympus Optical Co.,

D. Description of the Device

This instrument has been designed to be used with an Olympus endoscope to collect tissue within the upper and lower digestive tract and to extract the tissue sample through the biopsy forceps with suction.
The Olympus Biopsy Forceps XBO1-824-18/19/20 are composed with three major components as follows:

1. Biopsy Forceps (XBO1-824-18/19/20)
   The mechanism of subject device for collecting biopsied tissue is that biopsied tissue is caught onto Specimen trap by injected water through the biopsy forceps and it is possible to collect 5 samples continually.

2. Suction Tube (XBO1-824-18C)
   This device is for connecting the thumb ring valve to the suction source.

3. Specimen Trap (XBO1-824-18D)
   The Specimen Trap has a filter for the specimen to be aspirated through the Aspiration Lumen, which can be attached onto the proximal section of the Biopsy Forceps. The Specimen Trap is comprised with five independent filters, which are arrayed serially. After it catches the specimen, the filter that holds the specimen, is extruded from the proximal handle of the Biopsy Forceps, and snapped off into an individual section. To avoid unexpected breakage of the Trap, the Trap Support guides the sections of the Traps. When the section of the Specimen Trap is inserted into the proximal handle, it will make a "click" sound, and the first Trap will be centered at the axis of the Aspiration automatically.

E. Intended Use of the device

This instrument has been designed to be used with an Olympus endoscope to collect tissue within the digestive tract and to extract the tissue sample through the biopsy forceps with suction.

F. Reason for not requiring clinical data

Compared to the predicate devices, "Biopsy Forceps XBO1-824-18/19/20" does not incorporate any significant changes in intended use, methods of operations, materials, or design that could affect the safety and effectiveness.